#### 109TH CONGRESS 1ST SESSION

## H. R. 870

To amend the Federal Food, Drug, and Cosmetic Act to provide enhanced criminal penalties for certain violations of the Act involving knowing concealment of evidence of a serious adverse drug experience, and for other purposes.

### IN THE HOUSE OF REPRESENTATIVES

February 16, 2005

Mr. Stark (for himself and Mr. Berry) introduced the following bill; which was referred to the Committee on Energy and Commerce

### A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide enhanced criminal penalties for certain violations of the Act involving knowing concealment of evidence of a serious adverse drug experience, and for other purposes.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Pharmaceutical Re-
- 5 search and Manufacturers Accountability Act of 2005" or
- 6 the "PhRMA Act of 2005".

# 1 SEC. 2. CONCEALMENT OF SERIOUS ADVERSE DRUG EXPE-

- 3 (a) Penalty for Knowing Concealment of Se-
- 4 RIOUS ADVERSE DRUG EXPERIENCE.—Section 303 of the
- 5 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333)
- 6 is amended by adding at the end the following:

RIENCE.

- 7 "(h) An individual who violates a provision of section
- 8 301 shall be imprisoned for a term of a minimum of 20
- 9 years and a maximum of life, fined not more than
- 10 \$2,000,000, or both, if—
- 11 "(1) the individual is employed as the chief ex-
- ecutive officer or a member of the senior executive
- management group of the manufacturer of a drug;
- 14 and

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- 15 "(2) the violation involves, with respect to such
- drug, knowing concealment by the individual of evi-
- dence of a serious adverse drug experience (as that
- term is defined in section 505(0).".
- 19 (b) Annual Attestation by CEO Regarding Any
- 20 Serious Adverse Drug Experience.—The Federal
- 21 Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)
- 22 is amended—
- 23 (1) in section 505 (21 U.S.C. 355), by adding
- at the end the following:
- 25 "(o) Annual Attestation by CEO Regarding
- 26 Any Serious Adverse Drug Experience.—

1	"(1) REQUIREMENT.—For each drug for which
2	an approval of an application filed under subsection
3	(b) or (j) is in effect, the Secretary shall require the
4	chief executive officer of the manufacturer of the
5	drug to submit a separate, written attestation on an
6	annual basis—
7	"(A) stating that the manufacturer has
8	disclosed to the Secretary all evidence of any se-
9	rious adverse drug experience related to the
10	drug; and
11	"(B) describing the process by which the
12	manufacturer ensures that such disclosure has
13	occurred.
14	"(2) Definitions.—For purposes of this sub-
15	section:
16	"(A) The term 'evidence of any serious ad-
17	verse drug experience' includes any evidence of
18	a serious adverse drug experience that—
19	"(i) is obtained by the manufacturer
20	involved from any source of information,
21	foreign or domestic, including any informa-
22	tion obtained from a clinical trial con-
23	ducted before or after approval of the
24	drug, from postmarketing surveillance of

1	the drug, or from a postmarketing report
2	by a physician; or
3	"(ii) is required by any provision of
4	this Act to be reported by the manufac-
5	turer to the Secretary.
6	"(B) The term 'serious adverse drug expe-
7	rience' means an adverse drug experience occur-
8	ring at any dose that results in—
9	"(i) death, a life-threatening adverse
10	drug experience, inpatient hospitalization,
11	prolongation of existing hospitalization, a
12	persistent or significant disability or inca-
13	pacity, or a congenital anomaly or birth
14	defect; or
15	"(ii) a medical event that, based on
16	appropriate medical judgment, may jeop-
17	ardize the patient or subject and may re-
18	quire medical or surgical intervention to
19	prevent one of the outcomes listed in
20	clause (i).
21	"(3) Initial attestation.—The Secretary
22	shall require that the first attestation under this
23	subsection for a drug be submitted—
24	"(A) in the case of a drug for which ap-
25	proval of an application filed under subsection

1	(b) or (j) is in effect on the date of the enact-
2	ment of this subsection, not later than 1 year
3	after such date; and
4	"(B) in the case of any other drug, not
5	later than 1 year after the the date of such ap-
6	proval for the drug.
7	"(4) Failure to submit.—If the chief execu-
8	tive officer of a manufacturer of a drug for which
9	an approval of an application filed under subsection
10	(b) or (j) is in effect fails to submit a timely attesta-
11	tion for the drug as required by paragraph (1), the
12	Secretary—
13	"(A) may issue an order withdrawing ap-
14	proval of the application; and
15	"(B) shall not revoke such an order, or
16	otherwise approve or reinstate the application,
17	unless—
18	"(i) the Secretary conducts a review
19	of the drug's safety;
20	"(ii) the Secretary determines that
21	the drug is safe for use; and
22	"(iii) the manufacturer reimburses the
23	Secretary for the costs of such review and
24	determination.

1	"(5) Supplemental information.—In con-
2	ducting a review under paragraph (4)(B)(i), the Sec-
3	retary may require the manufacturer of the drug in-
4	volved to submit supplemental information on the
5	drug's safety.";
6	(2) in section 301 (21 U.S.C. 331), by inserting
7	at the end the following:
8	"(hh) The failure to submit an attestation in accord-
9	ance with section 505(o)."; and
10	(3) in section 303 (21 U.S.C. 333), as amended
11	by subsection (a), by adding at the end the fol-
12	lowing:
13	"(i)(1) A person who violates section 301(hh) by fail-
14	ing to submit an attestation in accordance with section
15	505(o) shall be fined—
16	"(A) in the case of an individual, in accordance
17	with title 18, United States Code; and
18	"(B) in the case of any other person, not more
19	than \$1,000,000.
20	"(2) Each 30-day period during which such violation
21	continues shall constitute a separate offense.".
22	(c) Deadline for Postmarketing Studies.—
23	(1) In General.—The Federal Food, Drug,
24	and Cosmetic Act (21 U.S.C. 301 et seq.) is amend-
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1	(A) in section 505 (21 U.S.C. 355), as
2	amended by subsection (b)(1), by adding at the
3	end the following:
4	"(p) Deadline for Postmarketing Studies of
5	Drugs.—
6	"(1) Requirement.—If the Secretary requires
7	the manufacturer or sponsor of a drug to conduct a
8	postmaketing study of the drug, the Secretary shall
9	require the manufacturer or sponsor to complete the
10	study by a specified deadline.
11	"(2) Extension.—On request, the Secretary
12	may extend a deadline established under this sub-
13	section.";
14	(B) in section 301 (21 U.S.C. 331), as
15	amended by subsection (b)(2), by inserting at
16	the end the following:
17	"(ii) The failure to complete a postmarketing study
18	by the deadline established by the Secretary for such study
19	under section 505(p)."; and
20	(C) in section 303 (21 U.S.C. 333), as
21	amended by subsections (a) and (b)(3), by add-
22	ing at the end the following:
23	"(j) A person who violates section 301(ii) by failing
24	to complete a postmarketing study for a drug by the dead-
25	line established by the Secretary for such study under sec-

- 1 tion 505(p) shall be fined not more than \$5,000,000. Each
- 2 30-day period during which such violation continues shall
- 3 constitute a separate offense.".
- 4 (2) APPLICATION.—The amendments made by
- 5 this subsection apply only with respect to a drug for
- 6 which an application is filed under subsection (b) or
- 7 (j) of section 505 of the Federal Food, Drug, and
- 8 Cosmetic Act (21 U.S.C. 33) on or after the date of
- 9 the enactment of this Act.
- 10 (d) Prohibition Against Indemnification.—No
- 11 person shall indemnify the chief executive officer of a drug
- 12 manufacturer or any other individual for any fine incurred
- 13 under the amendments made by this Act.

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